EXHIBIT 23

VOL. VI, ISSUE 6/APRIL 4, 2007

Rx COMPLIANCE REPORT

EXCLUSIVELY DEVOTED TO PHARMACEUTICAL SALES AND MARKETING COMPLIANCE

State prosecutors say trickle of off-label cases will soon turn into a flood

Montana, Pennsylvania and Texas are latest to join wide-raging off-label cases

Montana last month became the seventh state to sue big pharma for illegal off-label promotion. State prosecutors and *qui tam* attorneys tell *Rx Compliance Report* that similar cases are likely to replace drug pricing cases as the predominant form of state litigation aimed at drug companies. Texas, which has led the states in pursuing drug pricing cases, is a case in point. Earlier this year, Texas joined a *qui tam* case against Janssen alleging, among other things, that the company illegally promoted the drug to adolescents. Texas Assistant Attorney General **Patrick O'Connell** describes that case as "a combination case" because the illegal off-label promotion involved a high-priced drug that had adverse consequences for an unapproved population. As a result, he maintains, the state was hit by every possible angle.

This is "a much different case" than the wave of drug pricing cases that have dominated the Texas docket to date, says O'Connell. He estimates it will take three to five years to litigate most of the remaining drug pricing cases. But off-label cases are another story. "We are just starting the off-label cases," he reports. "There are a number of these cases in the pipeline." ▶ *Cont. on page 5*

IN THIS ISSUE

Twenty-one states introduce False Claims Act legislation

Twenty-one states have introduced false claims legislation patterned after the federal False Claims Act within the last year, reports False Claims Act expert **John Boese**. Not surprisingly, he adds, the vast majority of these bills have been introduced since the Deficit Reduction Act (DRA) took effect on January 1, 2007.

"If all these bills are enacted, they would add to the false claims laws already on the books in seventeen states plus the District of Columbia," says Boese. The result, he says, would be 35 state jurisdictions with false claims laws modeled on the federal statute. "In that event," says Boese, "the sphere of influence governed by the federal FCA will continue its expansion." ▶ *Cont. on page 5*

▶ *Cont. from page 1*

Twenty-one states introduce False Claims Act legislation

According to Boese, a partner with Fried Frank in Washington, D.C., the new state False Claims Act statutes are likely to be essentially identical to the federal False Claims Act. The reason, he explains, is that under the DRA state awards from False Claims Act litigation increase by 10 percentage points only if the state has adopted a state False Claims Act law similar to the federal version.

While this is typically a busy period for state legislatures, says Boese, the recent surge in state False Claims Act bills was clearly prompted by the DRA. Others, he says, are designed to respond to last year's HHS OIG report that concluded that many existing state False Claims Act laws are not sufficiently similar to the federal False Claims Act law to qualify for the ten percent financial incentive.

Ironically, Boese noted upon release of the OIG's report, many of the state False Claims Act laws deemed inadequate by the agency, such as Texas, have been among the most effective. ■

- **Nancy Barr**, Fried, Frank, Harris, Shriver & Jacobson, Washington, DC, BarrNa@friedfrank.com
- **John Boese**, Fried, Frank, Harris, Shriver & Jacobson, Washington, DC, BoeseJo@ffhsj.com

Status of new and existing state False Claims Act laws

Twenty-one states have recently introduced new False Claims Act legislation, or amendments to existing False Claims Act laws, according to Fried Frank's **Nancy Barr**. "Most of these bills are virtually identical to the federal False Claims Act," she says. New Mexico recently passed a bill that was signed into law by the Governor. It has also been reported that New York passed a state budget that includes a state false claims law. "We have not seen the specific provisions of the new law," says Barr, "but understand that it is directed at health care fraud."

According to Barr, most of the recently introduced bills provide for a penalty range of between five and ten thousand dollars. However, she adds, some depart from the federal law on the relator's share percentage. The Colorado bill, for example, allows not less than 20 percent nor more than 30 percent if the state does not proceed with an action. That bill also adds an eighth area of liability for failure to disclose a false claim for an inadvertent submission of a false claim that is subsequently discovered, a provision found in several existing state false claims law, says Barr.

Some of the bills enlarge upon the federal statute of limitations, according to Barr. The Colorado and Iowa bills, for example, would both allow all actions to be commenced up to ten years after the violation. According to Barr, seventeen states have some form of false claims law. Thirteen of these (including the District of Columbia) are "general" laws applicable to all types of alleged fraud against the state while six others are directed solely at health care fraud.

The following page contains a rundown of existing state False Claims Act statutes along with proposed legislation.

Status of new and existing state False Claims Act laws

State	Existing general FCA statute	Existing healthcare fraud statute	Introduced new law or amendment to existing law
Arkansas			X
California	X		
Colorado			X
Connecticut			X
Delaware	X		
District of Columbia	X		
Florida	X		X
Georgia			X
Hawaii	X		
Illinois	X		
Indiana	X		
Iowa			X
Kansas			X
Louisiana		X	
Maine			X
Massachusetts	X		
Michigan		X	
Minnesota			X
Mississippi			X
Missouri			X
Montana	X		
Nevada	X		
New Hampshire		X	
New Jersey			X
New Mexico	X	X	
New York			X
North Carolina			X
North Dakota			X
Oklahoma			X
Pennsylvania			X
Rhode Island			X
South Carolina			X
Texas		X	X
Tennessee	X		
Virginia	X		

Source: Fried Frank Harris Shriver & Jacobson

NCSL reports more than two dozen state laws aimed at drug marketing

Already this year, more than two dozen states have proposed legislation requiring marketing disclosures by drug manufacturers, regulating DTC advertising, or prohibiting prescription information from being sold for commercial purposes, according to data released by the National Conference of State Legislatures (NCSL) last week. "The total U.S. spending on pharmaceuticals topped $213 billion in 2006, while an estimated 90 percent of Americans take one or more prescription medications in a year," said NCSL. "These facts help explain why, in 2007, prescription drug policies continue to attract widespread attention and action in state capitols."

"It is important to keep in mind that only a handful of the bills introduced each year are actually signed into law," says **Nikki Reeves** of the Washington, D.C. office of King & Spalding.

More than 500 pharmaceutical bills and resolutions have been filed for consideration in 2007 legislative sessions, according to NCSL, which says that two nationwide factors are driving legislative this year. The first is the Medicare prescription drug benefit, now in its second year. The second is a federal report released in February, which indicated that the annual increase in pharmaceutical spending had dropped from double-digits three years ago to just 5.8 percent in 2006. The report credited state and private sector actions with contributing to this economic change.

Disclosure bills proliferate

According to NCSL, the proposed laws cover a wide range of state-sponsored approaches, from creation of subsidies or discount programs, to promoting safer pharmaceuticals and regulating the management, marketing and distribution of prescription products.

One of the "hot" topics, reports NCSL, is drug marketing and advertising. A handful of states already require pharmaceutical manufacturers to disclose marketing expenses, including gifts to drug prescribers. During the first quarter of 2007, however, at least 27 states have proposed legislation requiring marketing disclosures by drug manufacturers, regulating DTC advertising, or prohibiting prescription information from being sold for commercial purposes.

Among those states are the following:

Arizona. "Would require full disclose of prescription drug marketing costs and gifts to prescribers over $25."

Hawaii. "Would require prescription drug ads to meet federal standards, public disclosure of clinical trial information, and drug manufacturers to pay fees to Department of Health to fund a public education initiative on clinical trials and drug safety."
Illinois. "Would create a Prescription Drug Ethical Marketing Act that would require every manufacturer and labeler in the state to disclose the value, nature, and purpose of any gift, fee, payment, subsidy, or other economic benefit provided in connection with detailing or promotional activities by the company, directly or through its pharmaceutical marketers, to any physician, or any other prescriber in the state."

Maine. "Would prohibit the use of false or misleading prescription drug advertisements in the State by prescription drug manufacturers and also prohibits the use of language recommending the public to ask physicians about the use of any prescription drug."

Massachusetts. "Would provide for the disclosure of certain gifts made by pharmaceutical companies."

New York. "Would require pharmaceutical drug manufacturers and wholesalers to annually report, for disclosure to the general public, all of its gifts to health care practitioners that prescribe drugs when such gifts have a certain value."

Texas. "Would require pharmaceutical companies and marketers to report gifts valued at $75 or more on an annual basis to the Department of State Health Services and require that agency to post all such reports online. Would include an administrative penalty of up to $10,000 for each failure to report. Effective date January 1, 2009."

For more information, visit
http://www.ncsl.org/programs/health/drugbill07.htm

■ **Nikki Reeves**, King & Spalding, Washington, DC, NReeves@KSLAW.com

▶ *Cont. from page 1*

State prosecutors say trickle of off-label cases will soon turn into a flood

State off-label suits add complexity

Former federal prosecutor **Kathleen McDermott**, now a partner with Sonnenschein Nath & Rosenthal in Washington, D.C., says the willingness of states to become involved in an arena—namely off-label promotion—that traditionally has been the purview of FDA and the Department of Justice is a significant development.

In short, says McDermott, the state actions potentially make for great complexity both jurisdictionally and procedurally. "The state courts are an unknown jurisdiction and it may affect different strategies that are brought to bear on the government and the defense side," she explains. "What is unknown is the discretion, expertise, and resources that the states can bring to an action like this."

Nevertheless, she says, the predominant themes included in the various state off-label cases to date are very similar to off-label promotion allegations at the federal level. "The government is always going to look to see if the clinical data has been manipulated," she says. "It is going to look for safety issues. It is going to look for misleading or false statements."

Texas joins suit against Janssen

Earlier this year, Texas Attorney General, Greg Abbott joined a whistleblower lawsuit against Janssen Pharmaceutical, a subsidiary of Johnson & Johnson, in connection with its promotion of Risperdal, a "second generation" antipsychotic that far exceeds the cost of the older generation of antipsychotic drugs available in generic form.

According to O'Connell, Janssen's aggressive marketing caused the Texas Medicaid program to pay for $117 million of Risperdal over the last five years. "Not only has Texas paid this sum," he told a congressional committee last month, "but we do not know yet the increased costs of medical care for those children who used Risperdal and developed other symptoms such as diabetes."

When Janssen launched Risperdal in 1994, the only FDA-approved indication was for adults diagnosed with schizophrenia. Risperdal had no FDA-approved indication for any use in the child or adolescent population until October 2006, when it received a narrow indication for use in the limited population of children and adolescents diagnosed with irritability associated with autism.

The complaint states that Janssen sought to "distinguish" Risperdal from older antipsychotic drugs available for "pennies per pill rather than dollars per pill" by "improperly claiming that it was safer, more effective and more economical based upon improved outcomes in the treated populations."

Relator says TMAPs were co-opted

According to the suit, a major vehicle for Janssen's promotion of Risperdal was the Texas Medication Algorithm Project (TMAP). The suit alleges that Janssen "improperly influenced" at least one Texas state mental health program official through the payment of "substantial financial contributions" to secure a preferred position for Risperdal during the development and implementation of the TMAP.

"We are just starting the off-label cases," reports Texas Assistant Attorney General Patrick O'Connell. "There are a number of these cases" in the pipeline.

In the mid-1990s, the state of Texas began developing a set of medication protocols or "algorithms" to standardize the treatment of patients in public health programs with certain psychiatric disorders, which led to the creation and implementation of TMAPs. The complaint charges that Janssen "in conjunction with other manufacturers" of second generation antipsychotics "provided substantial financial contributions to and improperly influenced the development of these standardized public health protocols."

According to the 18-page complaint, at least one Texas mental health program decision-maker stated in speeches and other documents that funding for TMAP exceeded $6 million. The largest contributors to this fund were Janssen and the charitable arm of Johnson & Johnson, the Robert Wood Foundation. "These donations," the suit charges, "facilitated the designation of their profit-center drug, Risperdal, to

replace the cheaper, equally effective generics available to the state of Texas at that time."

The suit alleges that Janssen "viewed TMAP as a mechanism to overcome both the barriers created by the dearth of scientific evidence supporting widespread prescription of the newer medications and also the historic economic advantage of generic [antipsychotics]."

In Texas, the suit contends, Janssen "unduly influenced at least one mental health program decision-maker to become a chief proponent of Risperdal's inclusion in the TMAP protocol and to help secure TMAP's adoption and implementation."

In 1997 and 1998, TMAP proponents began working on the Texas Children's Medication Algorithm Project (TCMAP), the suit further charges.

According to the complaint:

> Defendant's improper influence infected this process as well. As a result of the continuing improper relationship between Defendants and at least one Texas mental health program decision maker, Defendants product, Risperdal, received a preferential recommendation as a medication of choice on the TCMAP algorithms used to treat children and adolescents. Defendant's product did not have an FDA-approved indication for use in children and adolescents when it was placed on the TCMAP algorithms.
>
> After the adoption of these new programs in Texas, Defendants experienced a significant increase in prescriptions and sales of Risperdal throughout the state. TMAP and TCAMP proved to be powerful marketing tools for Risperdal. Driven by these gains and revenues, Defendants turned to developing a concerted marketing plan to replicate these programs, and the dramatic revenue and market share generated by TMAP and its progeny, in other states. Defendants bypassed governmental safeguards and scientific review by promoting TMAP and the related child and adolescent algorithms, TCMAP as "treatment models" developed by panels of "experts." Defendants relied upon paid consultants on their expert consensus panels, peer-to-peer, or "viral," marketing strategies and administrative decisions made by a select few public officials to facilitate the adoption of TMAP-like programs in other states. To date, at least seventeen states, including Texas, have implemented TMAP or are in the process of doing so. In effect, TMAP became the standard-bearer for Defendants' Risperdal marketing plan.
>
> Based upon Risperdal's dramatic market success as a result of its inclusion in TMAP and its progeny, defendants began a concerted campaign to encourage other states to adopt similar programs. As part of the Defendant's scheme to have other state governments adopt medication algorithms, Defendant's improperly influenced state mental health program decision-makers with trips, perks, travel expenses, honoraria and other payments and also paid these decision-makers to speak in their official capacities to promote the Defendant's scheme.

To read the entire 18-page complaint, go to: http://www.rxcompliancereport.com/resources.html

State employee brings Texas suit

The suit was originally filed in 2004 by Allen Jones, an employee in Pennsylvania's Office of the Inspector General (OIG) from May 2002 until June 2004. As an OIG investigator, Jones had investigated allegations of impropriety during Pennsylvania's efforts to implement PENNMAP, a modified version of TMAP.

The complaint alleges that Janssen "improperly influenced state mental health program decision-makers with trips, perks, travel expenses, honoraria and other payment."

According to the complaint, he had "uncovered some of the facts" underlying the complaint while conducting an investigation for the Pennsylvania OIG. However, Allen maintains that after his on-site interviews with Janssen personnel, his supervisor told him that the investigation would not cover drug companies and should focus instead on a fairly low-level state employee.

The complaint continues:

> When Jones pressed for an explanation for the limited nature of the investigation and the retaliation he was facing, one of his managers stated that: "Drug companies write checks to politicians—they write checks to politicians on both sides of the aisle." Thus, Relator Jones was meant to understand that political pressures brought on by drug companies' influence prevented the Pennsylvania OIG from doing its job and safeguarding taxpayer funds. When Jones kept pressing to investigate the full scope of the wrongdoing, his supervisors removed him as lead investigator on the case in retaliation for those efforts.

According to **Linda Reig**, a partner with Porzio Bromberg in Morristown, N.J., the notion of a whistleblower action by an OIG investigator who claims his investigation was "shut down" despite the uncovering of violations is startling. "The complaint suggests, in not so subtle terms, that the government's enforcement arm is bowing to political influence by not following through on an investigation poised to uncover further details on apparent misconduct," she says. Reig says she is unaware of any restrictions against an OIG investigator serving as a whistleblower. "Essentially, the False Claims Act casts a wide net for potential whistleblowers because the government wants to encourage anyone with knowledge of misconduct that results in defrauding of the government to come forward," she says. "But here the whistleblower reports on firsthand knowledge of alleged misconduct within the OIG, *not* the drug company."

The complaint charges that Janssen hired third-party contractors to conceal its control and funding of CMEs, Speaker's Bureaus, Advisory Boards, clinical research and other events and organizations.

"Perhaps the relator can quantify or develop some of the items in the public record independently after he left the government," speculated another attorney. "But to the extent that he talked with them as a state employee, I don't think it is admissible."

Wide-ranging scheme alleged

The complaint alleges that TMAP was just one part of Janssen's wide-ranging marketing scheme to increase psychotropic drug sales by exaggerating the benefits and minimizing the known adverse effects associated with the drug. "Having convinced numerous state governments to express a preference for the use of its product through its specialty sales division devoted to public sector marketing, the suit charges, Janssen set out to brand Risperdal as the drug of choice throughout the mental health community.

The suit continues:

> Through the use of a variety of marketing tools disguised as education, scientific research and patient advocacy literature, Defendant's sought to penetrate every segment of the medical provider and patient caregiver communities. Defendants identified an untapped market which it sought to exploit by promoting its product as a panacea for a range of mental illnesses, symptoms and disorders. Examples of these marketing tools include Continuing Medical Education programs (CMEs), Speakers' Bureaus, Advisory Boards, Investigator Initiated Research, company-funded patient advocacy literature, and trade publications. Defendants hired third-party contractors to conceal Defendant's control and funding of CMEs, Speaker's Bureaus, Advisory Boards, clinical research and other events and organizations to lend an air of independent consensus about the acceptance, benefits, and safety of Risperdal. For example, Defendant's Advisory Boards were often comprised entirely of key opinion leaders, including State Mental Health Directors, who were regularly treated to trips and conferences, with all expenses paid by Janssen. Central to all of these marketing vehicles were Defendant's claims that Risperdal was a safer, more effective medication which the mental health community should choose not only over the older, cheaper generic medications, but also over other available Atypicals. Defendants made these claims in direct contravention to FDA notices and warnings.

In contrast to Janssen's claims of safety, increased tolerance and effectiveness, the complaint contends, Risperdal "appears to be only as effective or, in some instances, less effective and less safe in both the adult population and the child and adolescent population." In fact, it charges, "the side effects in the child and adolescent population appear to be more pronounced and more serious."

- Defense attorneys speculate that if the case against Janssen is successful, this suit could be replicated in numerous states that have adopted similar practices.

Pennsylvania targets blockbuster drugs

On February 26, the Commonwealth of Pennsylvania filed a civil lawsuit against Eli Lilly, Astrazeneca, and Janssen claiming damages on behalf of the state's Medicaid and PACE programs. The complaint alleges that each company engaged in promotional practices for brand name "second generation" antipsychotic medications—Zyprexa, Seroquel and Risperdal, respectively— that encouraged over usage for inappropriate conditions, and withheld information about potential side effects.

As a result, the state argues that its medical benefits programs paid for unnecessary prescriptions, as well as treatment for the side effects. Enhanced damages are claimed under the Pennsylvania statutes governing false claims to these programs: double damages in the case of Medicaid and a $10,000 penalty for each act under the PACE statute. The claims are based on state law grounds such as negligence, as well as the statutes which govern the Medicaid and PACE programs.

The total amount of damages sought are not specified in the complaint. "At this time, the Commonwealth is not able to provide an estimate of the potential total damages which may be recovered for the benefit of these programs," says **Gary Miller**, deputy director of communications for Governor Rendell. "However, the Commonwealth has spent millions of dollars to pay for prescriptions for these three drugs."

"The Pennsylvania complaint reads like a screed," says one defense attorney. "It is non-stop ranting and raving about all the conduct that is alleged to have occurred over the last decade regarding off-label promotion."

Wide-ranging PA suit draws criticism

Reig says it is not surprising that the suit targets conduct by big drug companies marketing blockbuster drugs. "Governments have limited resources so it is not surprising that the lawsuit here is brought against big companies with highly profitable products," she says. However, Reig and other defense counsel were struck by the sweeping nature of the complaint. "The 67-page complaint throws in just about everything but the kitchen sink to explain how these antipsychotic drugs reaped substantial revenues in the relatively short time that each has been on the market," she says.

According to Reig, the strategic design of clinical trials, the support of continuing medical education programs, and the retention of physicians to assist the company in its promotional goals are just a few of the activities cited as evidence of the company's allegedly violative efforts to position their drugs for greater sales.

State off-label cases

Below is a table showing state off-label cases filed to date. Total sales for 2006 are also reflected.

	Risperdal	Serequol	Zyprexa
	$4.18	$3.4 billion	$4.36 billion
Alaska			X
Louisiana			X
Mississippi			X
Montana			X
New Mexico			X
Pennsylvania	X	X	X
Texas	X		
West Virgina			X

Another defense counsel took a similar view. "The Pennsylvania complaint reads like a screed," he asserted. "It is non-stop ranting and raving about all the conduct that is alleged to have occurred over the last decade regarding off-label promotion. But when you actually try to pin down the evidence that any of these companies did any of these things, it's not there."

For example, he points out, the complaint cites regulatory letters sent to the companies days after the products were launched in the late-1990s "as though that shows what they have been doing in the interval.

"There are no dates, documents, or exhibits, to tell you what they did," he says. "The complaint is adequate to get into the court room but I am not nearly as impressed by that complaint as I am by the one filed in Texas."

Zyprexa becomes off-label poster child

Montana became the seventh state to file suit against Eli Lilly March 14 alleging the company fraudulently marketed its antipsychotic drug Zyprexa for unapproved uses. Montana Attorney General Mike McGrath claims that Lilly gave kickbacks to doctors and improperly promoted the drug to nursing homes as a sedative.

The suit was brought under the state's False Claims Act and Consumer Protection Act.

The suit contends that Eli Lilly had reason to know that Zyprexa put users at risk for developing severe and harmful conditions including hyperglycemia, acute weight gain, diabetes mellitus, pancreatitis, cardiac problems and death.

Notwithstanding the limited uses of Zyprexa approved by the FDA—including the treatment of schizophrenia, the short-term use of acute mixed or manic episodes associated with bipolar disorder, and maintenance treatment of manic-depression—Eli Lilly marketed, advertised, and sold the drug for a number of non-approved "off-label" uses "including Alzheimer Disease, Geriatric Dementia, Tourette's Syndrome, Pervasive Developmental Delay, Autism, Anorexia Nervosa, and General Depression," the suit agues.

The suit contends that since 1996 Eli Lilly's strategy has been to aggressively market Zyprexa "by willfully misleading potential users about serious dangers resulting from the use of Zyprexa." According to the complaint, the company "undertook an advertising blitz, extolling the virtues of Zyprexa" that included advertisements, telephone conferences, live conferences, direct promotional presentations to doctors and other healthcare providers, and other promotional materials provided directly to Zyprexa users. The company "also advertised the use of Zyprexa for off-label uses, including geriatric dementia, pediatric symptoms, and for general depression."

LTC sales force cited

Among other things, the complaint charges, Lilly created a 280-person sales force to promote Zyprexa exclusively for off-label uses, specifically for long-term care facilities "to maximize off-label use of Zyprexa sales in elderly populations." The purpose and function of the LTC sales force was to market Zyprexa for "a litany on non-indicated uses to control elderly patients who presented with agitation, anxiety, insomnia, or otherwise presented with symptoms that required time intensive care

Kathleen McDermott joins Sonnenschein

Sonnenschein Nath & Rosenthal announced last week that Kathleen McDermott has joined the law firm as the newest member of its national Health Care Group. McDermott, a partner who will reside in Sonnenschein's Washington, D.C. office, is a nationally recognized health care fraud and abuse lawyer with 15 years of experience both in and out of government. As an Assistant U.S. Attorney in Maryland for eight years (1991–1999), McDermott served as the Health Care Fraud Coordinator, directing a multi-agency health care fraud task force. She also participated on both the Attorney General's Advisory Committee for Health Care Fraud and the FBI's Health Care Fraud Working Group and is a recipient of the HHS Inspector General's Integrity Award.

Since moving to private practice, she has defended some of the nation's largest and most prominent hospitals, health systems, clinical research organizations, medical device manufacturers and insurers in a wide range of complex government investigations and whistleblower actions. In addition to her government investigation and litigation practice, McDermott provides compliance and enforcement representation to pharmaceutical, device and clinincal research organizations on a broad array of issues.

She can be reached at 202/408-3274 or kmcdermott@sonnenschein.com.

through sedation," the complaint maintains.

The suit also alleges a host or illegal kickbacks to physicians in order to generate sales of Zyprexa.

A disgruntled LTC director

The complaint states that Mike Murray, a LTC director for Lilly sales reps in Florida was personally involved in implementing and overseeing Lilly's "illegal LTC sales practices" in that state along with "firsthand knowledge of the company's "corporate" endorsement of such practices nationwide, including Montana.

Among other things, the complaint charges, Lilly created a 280-person sales force to promote Zyprexa exclusively for off-label uses, specifically for long-term care facilities.

"By March of 2006," says the complaint, "Murray had become disgruntled with Lilly." Accordingly, it says, Murray met with upper corporate management to discuss a severance from Lilly and threatened to disclose information about the alleged off-label marketing scheme and kickback scheme unless he received "a beneficial severance." In July 2006, the complaint says, Murray accepted "a generous severance package" in exchange for a non-disclosure agreement.

■ **Linda Reig**, Porzio, Brombreg & Newman, Morristown, NJ, lpreig@pbnlaw.com

Resources available on-line

The following resources, referred to in this issue, are available at:
www.rxcompliancereport.com/resources.html

Montana off-label suit
LillyComplaint0306200.pdf

Pennsylvania off-label suit
Cmwlthcomplaint.pdf

Texas off-label suit
2006-11-30RelatorsFirstAmendedPetition-UnderSeal.pdf

Grassley seeks Zyprexa marketing and safety documents

On April 4, Senator Charles Grassley (R-IA) asked Eli Lilly for information related to the risks and marketing of Zyprexa. Grassley's request, which he said was prompted by allegations the company downplayed safety risks and engaged in other improper marketing practices, follows a familiar pattern. In recent years, the senior Republican lawmaker has used his position n the Senate Finance Committee to investigate numerous FDA-related issues.

Noting several pending products liability actions regarding Zyprexa, Grassley said he was seeking documents produced by Eli Lilly as part of that litigation. Specifically, he requested "all documents and materials, including, but not limited to, emails, letters, reports, and memoranda, that were made available to the court-appointed Plaintiffs' Steering Committee I and II pursuant to pretrial discovery in In re Zyprexa Prods. Liab. Litig." no later than April 25, 2007.

On December 20, 2006, says Grassley, he wrote Dr. David Egilman, a plaintiffs' expert, to request information and documents related to Zyprexa. Egilman responded by providing the Committee with a copy of a discovery order, dated December 15, 2006, instructing him to return Eli Lilly documents in his possession to the Lanier Law Firm.

On February 14, 2007, notes Grassley, Judge Jack Weinstein of the U.S. District Court for the Eastern District of New York issued a decision regarding the confidential Eli Lilly documents. The court enjoined several individuals from further disseminating the protected documents and ordered them to return any such documents and copies still in their possession or control.

"Contrary to what was reported in Judge Weinstein's decision," says Grassley, "the Committee's Chief Investigative Counsel, Emilia DiSanto, did not receive any protected documents related to Zyprexa from Mr. James Gottstein or Dr. Egilman. Nor did Mr. Gottstein or Dr. Egilman provide any protected documents related to Zyprexa to other Committee staff."

Now that the dispute regarding the dissemination of the documents is resolved, Grassley says the Committee should have access to those documents.

Leading state prosecutor outlines major fraud targets for Congress

Texas Assistant Attorney General Patrick O'Connell tells House Oversight Committee pharma is still in the crosshairs

The Texas Attorney General's Office is certainly not the only state AG's office to pay close attention to when it comes to pharmaceutical fraud cases. But it's fair to say it is the last one that should be overlooked.

Since its creation in 1999, a special Civil Medicaid Fraud Section within the AG's office, headed by Patrick O'Connell, has been in the vanguard of drug pricing cases. While the office has pursued health care claims against doctors, hospitals and other providers, the overwhelming majority of its time and efforts have been concentrated on drug manufacturers. Given O'Connell's recent testimony before the House Committee on Government Reform and Oversight, there is no sign that is going to change in the foreseeable future.

O'Connell told the committee last month the reason for this is simple: Whistleblowers have brought cases against drug companies that "dwarfed" the cases against other providers. "Because of the limited number of staff and resources we can bring to any one case," he explained, "we chose to pursue those cases which provided the greatest recovery for the Medicaid program."

O'Connell makes no secret that he expects Texas to bring many more off-label cases in the wake of the state's intervention in a suit against Janssen. But he also highlighted the following areas as ripe for fraud and abuse:

Rebate fraud

Drug companies are required to pay rebates to the state Medicaid programs based on either a percentage of the Average Manufacturer Price (AMP) or the difference between the AMP and the manufacturer's "Best Price" as reported to CMS. However, O'Connell said some manufacturers have failed to accurately report their AMP and/or Best Price, and, as a result, have failed to extend their lowest price to the Medicaid program. He said methods used to perpetrate this fraud include fraudulent reporting AWP or the wholesale cost of drugs, fraudulent reporting of AMP by failing to account for discounts, rebates and chargebacks, and fraudulent reporting of Best Price through the use of what is known as nominal pricing and/or bundling.

1. Reports of false AWP or Wholesale Cost. The rebate system assumes that the Medicaid program has paid an estimated acquisition cost that is reasonably close to the actual acquisition cost. The rebate then brings the program's price down near the Best Price, O'Connell explained. "If the estimated acquisition cost is inflated due to fraud," he said, "the rebate does not bring the net price to the program down to the Best Price."

O'Connell told Congress that some manufacturers have failed to accurately report their AMP and/or Best Price.

Congress attempted to resolve this problem in the last session by changing the methodology of creation of the Federal Upper Limit (FUL) on multi-source drugs to 250 percent of the lowest published AMP, noted O'Connell. "Our experience in Texas shows that multi-source drugs are sold in a very narrow range in the market place," he told the committee, "and we are concerned that an FUL of 250 percent does not limit the potential for fraud enough."

2. Reporting of AMP/Best Price. O'Connell pointed out that the reporting of AMP/Best Price is supposed to take into account all rebates, discounts and chargebacks for sales to the retail class of trade. "The lower the AMP, the lower the rebate," he said. "So, if discounts are applied in a calculation of AMP that should not have been applied, the AMP is fraudulently reduced."

"The AMP for a branded product is 15.1 percent of the AMP or the difference between AMP and Best Price, whichever is greater," he explained. "If discounts are not applied to the Best Price calculation, the Best Price remains artificially high

and the difference between AMP and Best Price is reduced. Consequently, the rebate is reduced."

According to O'Connell, this fraud can be accomplished in a number of different ways. The primary method, he said, is to provide free goods and services, educational grants or other valuable monetary incentives to influence the purchasing decision. "These incentives are not reported as discounts," he added, "thereby artificially inflating the Best Price."

3. Bundling fraud. Bundling is the practice of selling a number of drugs by a manufacturer with the provision of a discount so long as the purchase is of all of the drugs in the transaction. "For example, a manufacturer tells a provider that they can obtain a 25 percent discount on four of the manufacturer's drugs so long as the provider buys a particular drug at a higher undiscounted price," he said. "Under the current rules, the discount is to be apportioned across all of the drugs in the transaction," he continued. "If the discount is all applied to the generic drugs in the transaction, the rebate for the generics stays unchanged. However, the rebate for the branded products could have been affected because the Best Price for the branded product could have been lower than the reported Best Price."

4. Nominal pricing fraud. In addition, when calculating Best Price, manufacturers do not have to include sales to entities at "merely nominal pricing," noted O'Connell. In order to allow manufacturers to provide product to charitable entities at little or no cost without requiring them to use that price to calculate their rebates, CMS issued a ruling that said that any sale at less than 10 percent of AMP was "nominal," he explained.

However, O'Connell cautioned, some manufacturers have illegally used this provision to discount the prices of their drugs to their normal customers without reporting a lowered Best Price. For example, he said, some manufacturers have provided their drug to hospitals at eight percent of the regular rate under an agreement with the hospital that the drug is used more than 80 percent of the time or if the drug has been declared to be the preferred drug on the hospital's formulary.

"In other words," he told the committee, "the low price is tied to a performance measure. We believe this is not 'merely nominal,' and it has the effect of improperly influencing prescription decisions at the hospital."

Misrepresentation of safety and effectiveness

"The Texas Medicaid program has for years had an open formulary," said O'Connell. "That is, if a drug was approved by the FDA and a drug manufacturer signed a rebate agreement and the manufacturer asked to be placed on the Texas Medicaid formulary, the drug was placed on the formulary and was reimbursable under the Texas Medicaid rules." But here is the catch, he added. "When the drug manufacturer asks for its drug to be included on the formulary, the manufacturer must swear to its safety and efficacy. If, in fact, the drug is not safe, the Medicaid program is reimbursing for a drug that it would not otherwise have paid for.

Some manufacturers have illegally used the nominal price provision to discount the prices of their drugs to their normal customers without reporting a lowered Best Price, said Texas Attorney General Patrick O'Connell

The Texas Medicaid program paid for $57 million for Vioxx prior to the time Merck voluntarily removed it from the market, which led Texas and a number of other states to sue under their False Claims Act statutes for the return of these funds.

"When Texas and other states pursue these types of Medicaid fraud, we are often met with a scorched earth defense where we are forced into extensive pre-trial discovery battles," he concluded. "These maneuvers not only increase the cost to the state to try the lawsuit but place an inordinate burden on the Medicaid program." ■

■ **Patrick O'Connell**, Patrick J. O'Connell, Assistant Attorney General, Chief, Civil Medicaid Fraud Section, Texas Attorney General's Office

One week away!

Drug and Device Compliance Boot Camp: Training the Sales Force

Wednesday, April 11, 2007 to Thursday, April 12, 2007
The Warwick Hotel , New York, NY
www.americanconference.com

AGENDA

Day 1 – Wednesday, April 11, 2007

8:00 Registration and Continental Breakfast

8:45 Chairperson's Opening Remarks

Gary Del Vecchio, Director, Compliance Education, U. S. Healthcare Law Compliance, Bristol-Myers Squibb

9:00 Bringing Compliance Alive for Sales Reps by Speaking Their Language

Regina Cavaliere, Senior Counsel, U. S. Healthcare Law Compliance, Bristol-Myers Squibb

Gary Del Vecchio, Director, Compliance Education, U. S. Healthcare Law Compliance
Bristol-Myers Squibb

James Oliver, Attorney, Datascope Corp.

10:15 Making Information Sink in by Keeping Training Sessions Engaging

Dale Hougham, Director, GSC Compliance, Boston Scientific Corporation

Kathleen Lundberg, Senior Vice President, Chief Compliance Officer, Global Compliance, CRM/CS, Boston Scientific Corporation

11:15 Implementing Successful Testing and Monitoring Models for the Field-Based Sales Force

Jennifer Bragg, Partner, King & Spalding LLP

Observing sales reps directly in the field

12:15 Networking Luncheon

1:45 Bridging the Gap Between Knowledge and Performance: Using Simulation to Improve Compliance training Results

Koreen Olbrish, Client Service Director, AXIOM Professional Health Learning

3:00 Bringing Compliance Closer to the Front of the Sales Force's Minds

Alan G. Minsk, Partner and Chair, Food and Drug Practice Team, Arnall Golden Gregory LLP

4:00 Comparing the Company's Sales Force Compliance Training Program to Competitive Programs

Gary Del Vecchio, Director, Compliance Education, U. S. Healthcare Law Compliance, Bristol-Myers Squibb

William T. Fitzgerald, Vice President, Global Compliance, Alcon Laboratories, Inc.

5:00 Conference Adjourns

Day 2 – Thursday, April 12, 2007

8:30 Continental Breakfast

9:00 Chairperson's Opening Remarks

Linda Pissott Reig, Principal, Porzio, Bromberg & Newman P.C.

9:15 Getting Down to Specifics: Training Sales Reps on the Hot-Button Issues in Recent Investigations

Darren W. Alch, Compliance Officer, Cyberonics, Inc.

Linda Pissott Reig, Principal, Porzio, Bromberg & Newman P.C.

10:45 Tailoring Compliance Training to the Company's Products, People, and Problems

John P. Oroho, Principal, Porzio, Bromberg & Newman P.C.

Janet L. "Lucy" Rose, President, Lucy Rose and Associates, LLC

1:15 Getting the Sales Managers on Board with the Compliance Message

Teresa I. Ford, Attorney, Law Offices of Teresa I. Ford, PC

Peter S. Henderson, Director, Ethics and Compliance, Roche Diagnostics Corporation

2:45 Compliance Training for the Multi-National Sales Force: Tactical Considerations for Developing and Delivering Content

Roger W. Louis, Chief Compliance Officer & Vice President, Healthcare & Regulatory Counsel, Genzyme Corporation

3:45 Conference Concludes

Master Class: Effectively Incorporating Complicated DRA Provisions Into Company Policies and Defense Strategies

2:00 p.m. – 5:00 P.M. (Registration opens at 1:30 p.m.)

Jonathan Diesenhaus, Partner, Hogan & Hartson LLP

Michael C. Theis, Partner, Hogan & Hartson LLP

Kathleen McDermott, Partner, Sonnenschein Nash & Rosenthal LLP

Special discount to RxCompliance subscribers

To register for this conference at a $200 discount, please use the following code: 720L07.RXC

Upcoming ACI conferences in May

Below is a list of American Conference Institute programs next month dealing with timely issues affecting drug and device companies. For more information on these and other ACI events, visit: www.americanconference.com/Pharmaceuticals_Biotech_Life_Sciences.htm

Anti-Corruption for Pharma & Life Sciences Minimizing Exposure Under Expansive Definitions of Foreign "Government Officials"

May 1-2, 2007
New York Marriott East Side , New York, NY

Interactive Workshops

April 30, 2007
FCPA and International Anti-Corruption 101 for the Pharmaceutical and Life Sciences Industries

May 2, 2007
Case Study: How to Conduct a Successful Internal FCPA Audit
Overcoming the Specific Challenges of Complying with the FCPA and Local Anti-Corruption Laws in China for Pharmaceutical and Life Sciences Companies

FDA Boot Camp
Basic Training for Products Liability and Patent

May 15-16, 2007
JW Marriott San Francisco , San Francisco, CA

Annual In-House Counsel Forum on Government Regulation of Prescription Drug Pricing
Rx Drug Pricing Boot Camp
Intensive training in essential pricing concepts, methodologies, and strategies relative to key government payor programs

May 17-18, 2007
Crowne Plaza , San Francisco, CA

"Big Four"
Pharmaceutical Pricing Boot Camp
Intensive training in the essential pricing concepts and methodologies related to VA, DoD, PHS, and Coast Guard programs

May 21-22, 2007
Affinia Manhattan Hotel , New York, NY

American Health Lawyer's

Life Sciences Law Institute

April 25-27, 2007
Parc 55 Hotel • San Francisco, CA

The program is designed to address the unique issues faced by in-house and outside counsel for pharmaceutical companies, biotechnology companies, device manufacturers, academic medical centers, and healthcare providers who have relationships with the life sciences industry.

Daniel Meron, General Counsel at the Department of Health and Human Services, will give this year's keynote address. Following the keynote, **Linda Freidman** from Astellas, and **Bruce Garren** from Edwards Lifesciences Corporation will discuss The In-Box Issues for Biotech, Drug and Device General Counsels.

Breakout sessions will include:

- Coverage, Reimbursement and Fraud and Abuse Basics for FDA (and New) Lawyers
- FDA Basics for Healthcare (and New) Lawyers
- Conducting Effective Internal Investigations and Managing the Whistleblower Threat
- Postmarket Safety Issues for Devices
- Recent Life Sciences Corporate Integrity Agreements: Consequences for Compliance Auditing and Monitoring
- Medicare Part B Coverage, Billing and Payment for Drugs and Biologics Furnished in an Outpatient Setting
- Global Compliance Challenges for Life Sciences Companies
- Off-Label Promotion: Current Government Theories/Legal and Policy Defenses
- Pharmaceutical Industry Data: What Litigating and Compliance Attorneys Need to Know

The program begins at 1:00 pm on Wednesday, April 25 and ends at 3:50 pm on Friday, April 27.

For more information or to register, visit: www.healthlawyers.org or call 202/833-0766.

Rx COMPLIANCE REPORT
EXCLUSIVELY DEVOTED TO PHARMACEUTICAL SALES AND MARKETING COMPLIANCE

Matthew Hay, Editor & Publisher
Jonathan Wilkenfeld, Senior Writer

46709 Bullfinch Square, Sterling, VA 20164
Phone: 703/501-2019
RxCompliance@aol.com
www.rxcompliancereport.com

Rx Compliance Report is published 24 times a year. Subscription price is $597 per year.